REMARKS

In the Office Action, claims 19-22 were rejected under 35 U.S.C.§112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that the applicant regards as the invention.

Reconsideration is requested.

Claims 19-22 have been amended provide a proper antecedent basis for the terms in the claims. For these reasons, it is requested that this ground of rejection be withdrawn.

In the Office Action, Claims 1, 3-8, 13-14 and 17-22 were rejected under 35 U.S.C.§103(a) as being unpatentable over Meignant et al. (Meignant) in view of Andoh et al. (Andoh) or Tovey et al. (Tovey) or Remington's Pharmaceutical Sciences.

Reconsideration is requested.

Meignant teaches a process for making a formulation, including granulating the components and mixing them together. This procedure may not be applied to calcium phosphate formulations when the calcium phosphate is used in the quantities indicated in the present application. The examples in Meignant utilize soluble calcium salts or calcium carbonate but do not utilize calcium phosphate which is the material recited in amended claim 1. It must be noted that calcium phosphate is an insoluble salt of calcium. Meignant uses a dry/wet process and teaches a granulation of the calcium salt (in particular calcium carbonate) where a part of the binder is used in a dry condition and the remaining part of the binder is utilized in the form of an aqueous solution before adding the other excipients. In the claimed invention, no water is used and the process is therefore totally performed under dry conditions which is made possible by the selection of the specific binders recited in the claims.

It is important to note that the calcium phosphate, used in the amended claims, is insoluble and

therefore poses problems of granulation when used in large quantities (as it is the case here). The traditional process of ''wet granulation'' does not produce a satisfactory granulation even using different binders. Analogously unsuccessful results are obtained when a mixed dry/wet process as the one described by Meignant with PVD was performed as shown by the data in the attached declaration.

In addition, it should be noted that the formulation contains Vitamin D which is more susceptible to oxidation in the presence of moisture which is to be avoided in formulating products that contain Vitamin D. Therefore the dry method was considered to be the solution to the granulation problem but since that did not work it was necessary to find liquid binders that would provide an appropriate granulation.

On the other hand Andon and Tovey prepare solid tablets to swallow while Remington generally describes binders without any mention of calcium phosphate or Vitamin D formulations. There is no information in Andoh, Tovey or Remington that teaches the necessity of using liquid binders for a calcium phosphate-Vitamin D formulation.

It is clear that in order to correctly granulate the presently claimed formulations which contain large quantities of calcium phosphate, the presence of a liquid binder is necessary while a solid binder must be avoided. The enclosed Declaration reports actual test data based on attempts to use solid binders in a dry granulation method where other ingredients are used in the same concentrations. In other words the binders cited in Andoh, Tovey and Remington are not suitable for the formulation of a calcium phosphate-Vitamin D formulation.
The four binders expressly cited in Claim 1 (i.e. PEG 400, ethylene glycol, paraffin liquid and silicon oil) allowed the obtaining of useful granulates. In particular liquid paraffin and silicon oil (because of a rather unpleasant

taste and appearance of the corresponding aqueous dispersion) gave granulates which were considered more suitable for the preparation of solid tablets .For these reason, it is requested that this ground of rejection be withdrawn.

An early and favorable action is earnestly solicited.

Respectfully submitted,

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